

Designation Run Report

Strait, Matthew - Plaintiffs' Submission

Strait, Matthew 05-31-2019

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16:2 Do you see that?

16:3 A. Yes.

16:4 Q. When it says "your," you understand

16:5 that that is referring to the Drug Enforcement

16:6 Administration, correct?

16:7 A. Correct.

16:8 Q. And that today testifying here, you

16:9 are testifying on behalf of the Drug

16:10 Enforcement Administration.

16:11 A. Correct.

16:12 Q. So when we -- so when I refer to

16:13 "you" in this deposition, unless I refer

16:14 specifically to you, I'm referring to the Drug

16:15 Enforcement Administration, correct?

16:16 A. Yes.

16:17 Q. Do you understand that the subject

16:18 matter on which you are authorized to be -- to

16:19 -- to testify today is -- is included here in

16:20 this section under Topic 21?

16:21 A. Yes.

16:22 Q. What is your current position at the

16:23 Drug Enforcement Administration?

16:24 A. I am the senior policy advisor to

16:25 the assistant administrator for the diversion

17:1 control division.

17:2 Q. And what is your responsibility as

17:3 the senior policy advisor?

17:4 A. I report directly to the assistant

17:5 administrator and advise him on policy matters

17:6 that are relevant to the diversion control

17:7 program, the mission of the program.

17:8 Q. Okay. Prior to your current role as

17:9 senior policy advisor, what was your role at

17:10 Drug Enforcement Administration?

17:11 A. I've had several roles over the last

17:12 20 years. And I can get into as much or as

17:13 little detail as -- as you like about those.

17:14 Q. Let's -- let's take the last let's

17:15 say five years.

17:16 A. Okay. I've been back in the

clear

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	17:17 diversion control program since June of 2017	
	17:18 serving in the capacity I'm in now.	
	17:19 Prior to that, for two and a half	
	17:20 years prior to, I was the section chief for	
	17:21 DEA's congressional affairs section and	
	17:22 therefore had the liaison responsibilities for	
	17:23 the agency with congress.	
	17:24 Q. When you say "liaison	
	17:25 responsibilities," can you give me a little	
	18:1 more detail about what that means?	
	18:2 A. Sure. So in -- in congress's role	
	18:3 of doing oversight over the federal government,	
	18:4 including DEA, my roles would have been	
	18:5 prepping witnesses for congressional testimony,	
	18:6 providing formal or informal views on	
	18:7 legislative proposals that affected DEA, and	
	18:8 also working with the interagency on issues of	
	18:9 interest in which other agencies might be	
	18:10 testifying or working with congress on matters	
	18:11 that impact DEA.	
	18:12 Q. The Government Accountability Office	
	18:13 is a legislative agency, correct?	
	18:14 A. Yes.	
	18:15 Q. So in your role as liaison between	
	18:16 DEA and congress, did your responsibilities	
	18:17 intersect with the Government Accountability	
	18:18 Office?	
	18:19 A. Yes.	
	18:20 Q. Were -- would you have been aware of	
	18:21 investigations and reports of the Government	
	18:22 Accountability Office into the Drug Enforcement	
	18:23 Administration?	
	18:24 A. Yes.	
19:14 - 19:15	Strait, Matthew 05-31-2019 (00:00:06)	MS04.5
	19:14 Q. Can you explain for the jury what	
	19:15 the Government Accountability Office is?	
19:21 - 20:02	Strait, Matthew 05-31-2019 (00:00:25)	MS04.6
	19:21 THE WITNESS: The GAO largely is	
	19:22 charged with assisting congress in their	
	19:23 oversight role. So in my times -- in many	

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20:04 - 21:06	<p>19:24 instances, from -- from my experience, GAO 19:25 reports or requests come from members of 20:1 congress as they try to understand better 20:2 things that they hear from the general public.</p> <p>Strait, Matthew 05-31-2019 (00:01:27)</p> <p>20:4 Q. In your experience, how does the GAO 20:5 go about its -- it's role in -- in oversight? 20:6 A. I believe they're very methodical. 20:7 I think they do really good work. 20:8 Q. And -- and what kind of work do they 20:9 -- so you mentioned earlier that members of 20:10 congress may request the GAO to investigate 20:11 something. 20:12 When you say "they're very 20:13 methodical," what do you -- what do you mean by 20:14 that? 20:15 A. Just the way they go about doing 20:16 their business. The work that they do, they 20:17 generally come in, have a kick-off meeting with 20:18 the -- the subject of their investigation, the 20:19 agency. They ask a number of very deliberative 20:20 questions. They seek responses in -- in 20:21 certain time frames. And there's oftentimes a 20:22 very persistent exchange of information 20:23 throughout their audit period. 20:24 They're very good at controlling 20:25 deadlines and helping congress get their 21:1 responses in -- in a timely fashion. 21:2 Q. When the GAO investigates let's say 21:3 the Drug Enforcement Administration and issues 21:4 recommendations, does the -- does -- does the 21:5 DEA take those recommendations seriously? 21:6 A. Absolutely. Yes.</p> <p>Strait, Matthew 05-31-2019 (00:00:53)</p> <p>21:14 Q. As a matter of course -- well, let 21:15 me ask it this way: What is typical -- what 21:16 are the kinds of internal processes for 21:17 responding to GAO recommendations? 21:18 A. Well, DEA has a whole GAO audit 21:19 liaison team whose sole function is to ensure</p>	<p>MS04.7</p> <p>MS04.8</p>
21:14 - 22:06		

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	21:20 that GAO is getting, one, responses to their 21:21 questions during the audit time frame when a -- 21:22 when a report is under consideration; but then 21:23 also, on follow-up, once recommendations are 21:24 made, our audit liaison team is consistently 21:25 working with the program office to what we call 22:1 close out a recommendation. 22:2 Q. And what does it mean to close out a 22:3 recommendation? 22:4 A. It means to address to the 22:5 satisfaction of GAO the recommendations that 22:6 they've made.	
23:10 - 23:13	Strait, Matthew 05-31-2019 (00:00:06) 23:10 BY MR. MASTERS: 23:11 Q. I'm handing you what has been -- 23:12 hold on a second -- what has been marked as 23:13 Exhibit 3.	MS04.9 P-20012.1
23:14 - 23:16	Strait, Matthew 05-31-2019 (00:00:11) 23:14 Can you identify this document? 23:15 A. This is the GAO's report known in 23:16 the -- known by GAO as GAO 15471.	MS04.10 P-20012.1.1
23:17 - 24:07	Strait, Matthew 05-31-2019 (00:00:36) 23:17 Q. And you -- you have seen this report 23:18 before, correct? 23:19 A. Correct. 23:20 Q. When did you first become aware of 23:21 this report? 23:22 A. Back in 2015. 23:23 Q. That was when the report was issued? 23:24 A. Yes. 23:25 Q. Were you aware of the -- of the 24:1 investigation prior to the issuance of this 24:2 report? 24:3 A. In my capacity in our congressional 24:4 affairs office, I was aware that the -- the 24:5 study was being undertaken. But I was not 24:6 aware of when it was going to culminate, when 24:7 it was going to be issued.	MS04.11
24:20 - 25:22	Strait, Matthew 05-31-2019 (00:01:36) 24:20 Q. Turning to Page 1 of the report --	MS04.12 P-20012.2

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24:21 or I should say the -- the very first page, the
 24:22 summary, the first full paragraph, the second
 24:23 sentence from the bottom states: "Federal
 24:24 internal control standards call for adequate
 24:25 communication with stakeholders."

P-20012.2.1

25:1 Do you see that?

25:2 A. Second from the bottom. I -- of the

25:3 first full paragraph?

25:4 Q. Yes.

25:5 A. "Federal" -- yes.

25:6 Q. Does the DEA agree with that

25:7 statement?

25:8 A. Yes.

25:9 Q. In this study the GAO was asked by

25:10 members of congress to review the adequacy of

25:11 DEA's communications and guidance with

25:12 distributors and pharmacies about their

25:13 regulatory responsibilities, correct?

25:14 A. And practitioners.

25:15 Q. Sorry. And practitioners.

25:16 So they were asked to look at the

25:17 communications and guidance between DEA and

25:18 distributors, pharmacies and practitioners?

25:19 A. Correct.

25:20 Q. And to conduct its investigation

25:21 into the communication and guidance with these

25:22 registrants, what did the GAO do?

25:25 - 27:16

Strait, Matthew 05-31-2019 (00:01:49)

MS04.13

25:25 THE WITNESS: They did a survey.

26:1 They conducted a survey for each of the

26:2 registrant populations.

26:3 BY MR. MASTERS:

26:4 Q. Was that a nationally representative

26:5 survey?

clear

26:6 A. They called it generalizable. They

26:7 interviewed -- they sent the survey out to 200

26:8 distributors, 300 pharmacies and 400

26:9 practitioners.

26:10 But for a point of consideration,

26:11 300 pharmacies, we have about 71,000 pharmacies

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26:12 presently. With our practitioner community, we
 26:13 have 1.7 million prescribers at present. So
 26:14 they -- they did 400. And they -- they used a
 26:15 statistical model to -- to make it
 26:16 generalizable to the public.

26:17 Q. And what about with distributors;
 26:18 how many distributors are there?

26:19 A. 200 of -- presently -- in the report
 26:20 they refer to 9 -- over 900, I think 945. But
 26:21 on the controlled substance side, we have 750.

26:22 Q. Okay. And same -- same with
 26:23 distributors as -- as with pharmacies and --
 26:24 and practitioners; they used a statistical
 26:25 model to make it generalizable with respect to
 27:1 distributors, right?

27:2 A. That's what's in their report, yes.

27:3 Q. They also interviewed 26 national
 27:4 associations and other nonprofit organizations,
 27:5 correct?

27:6 A. Correct.

27:7 Q. And they interviewed 16 government
 27:8 agencies from four different states?

27:9 A. That is correct.

27:10 Q. And in addition to the web-based
 27:11 surveys of all those registrants you mentioned,
 27:12 the national associations and the government
 27:13 agencies, the GAO also reached out to DEA for
 27:14 its perspectives on communications and guidance
 27:15 to registrants, correct?

27:16 A. That is correct.

28:12 - 29:03

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MS04.14

28:12 Q. That report indicates that the GAO
 28:13 interviewed DEA Office of Diversion Control
 28:14 officials, correct?

28:15 A. Correct.

28:16 Q. Who was interviewed?

28:17 A. I don't know specifically the names
 28:18 of the individuals that were interviewed, but
 28:19 they would have been senior officials within
 28:20 the diversion control.

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	28:21 At the time it was the Office of 28:22 Diversion Control. Now they are the Diversion 28:23 Control Division. 28:24 Q. And these senior officials would 28:25 have had personal knowledge and understanding 29:1 of the communications and guidance that DEA had 29:2 given to registrants in the past, correct? 29:3 A. Absolutely. Yes.	
29:16 - 30:13	Strait, Matthew 05-31-2019 (00:01:02) 29:16 Q. One of the issues that the GAO was 29:17 investigating was the adequacy of DEA's 29:18 guidance to distributors relating to suspicious 29:19 order monitoring, correct? 29:20 A. Yes. 29:21 Q. Did the GAO issue any 29:22 recommendations concerning DEA's guidance to 29:23 wholesale distributors relating to suspicious 29:24 order monitoring and reporting? 29:25 A. Let me go back to read the 30:1 recommendation. 30:2 Recommendation 2 was to -- 30:3 Q. Can -- before you begin, can you let 30:4 me know which page you're reading from? 30:5 A. Sure. I'm on Page 44 of the report. 30:6 Q. Okay. Great. I'm sorry. Please 30:7 continue. 30:8 A. Recommendation 2 was: "Solicit 30:9 input from distributors or associations 30:10 representing distributors and develop 30:11 additional guidance for distributors regarding 30:12 their roles and responsibilities for suspicious 30:13 orders monitoring and reporting."	MS04.15
		P-20012.51
		P-20012.51.1
30:14 - 30:18	Strait, Matthew 05-31-2019 (00:00:14) 30:14 Q. Now, in your understanding of the 30:15 GAO's report, that recommendation encompassed 30:16 both additional communications with 30:17 distributors and additional written guidance, 30:18 correct?	MS04.16
30:21 - 31:07	Strait, Matthew 05-31-2019 (00:00:30) 30:21 THE WITNESS: I just want to go back	MS04.17

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	30:22 and read specifically.	
	30:23 "Solicit input and develop	
	30:24 additional guidance for distributors."	
	30:25 It doesn't necessarily, as I	
	31:1 understand, separate between whether it be	
	31:2 verbal or whether it be in writing.	
	31:3 BY MR. MASTERS:	
	31:4 Q. Okay. Did -- did the report say	clear
	31:5 that some of the distributors wanted more	
	31:6 guidance?	
	31:7 A. Yes.	
31:08 - 31:16	Strait, Matthew 05-31-2019 (00:00:26)	MS04.18
	31:8 Q. In fact, more than half of the	
	31:9 distributors who responded to the open-ended	
	31:10 questions in the survey said they needed more	
	31:11 communication, information and inter --	
	31:12 interactions with DEA, correct?	
	31:13 A. Yes. I believe that's on Page 26 of	P-20012.33
	31:14 the report, if I'm not mistaken.	
	31:15 Q. That is correct. You have a great	
	31:16 memory.	
31:17 - 32:01	Strait, Matthew 05-31-2019 (00:00:24)	MS04.19
	31:17 In the middle of paragraph beginning	P-20012.33.1
	31:18 with "Furthermore," it says: "Furthermore, in	
	31:19 response to an open-ended question about what	
	31:20 additional interactions they would find helpful	
	31:21 to have with DEA, more than half of the	
	31:22 distributors that offered comments said they	
	31:23 needed more communication or information from	
	31:24 or interactions with DEA."	
	31:25 Did I read that correctly?	
	32:1 A. That -- that looks correct, yes.	
32:02 - 33:02	Strait, Matthew 05-31-2019 (00:01:12)	MS04.20
	32:2 Q. Did the GAO say that the DEA was	clear
	32:3 giving more written guidance to pharmacies and	
	32:4 physicians than it was to distributors?	
	32:5 A. I think that's a fair	
	32:6 characterization. The report discussed the	
	32:7 pharmacist manual and the practitioner's	
	32:8 manual, which were written publications on the	

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	32:9 diversion web site. And there is no such	
	32:10 manual for DEA registered distributors.	
	32:11 Q. Let's -- let's go ahead and turn to	
	32:12 that section of the report. It's one page over	P-20012.32
	32:13 on Page 25.	
	32:14 A. Uh-huh.	
	32:15 Q. Would you please read for the record	
	32:16 the first two sentences of the second	P-20012.32.1
	32:17 paragraph.	
	32:18 A. "Some survey responses indicate that	
	32:19 additional guidance for distributors regarding	
	32:20 suspicious orders monitoring and reporting, as	
	32:21 well as more regular communication, would be	
	32:22 beneficial.	
	32:23 For example, while DEA has created	
	32:24 guidance manuals for pharmacists and	
	32:25 practitioners, the agency has not developed a	
	33:1 guidance manual or a comparable document for	
	33:2 distributors."	
33:03 - 33:14	Strait, Matthew 05-31-2019 (00:00:29)	MS04.21
	33:3 Q. Did the GAO conclude that additional	clear
	33:4 guidance for distributors regarding suspicious	
	33:5 order monitoring and reporting would be	
	33:6 beneficial?	
	33:7 A. Their recommendation is as we had	
	33:8 previously discussed.	
	33:9 Q. And -- and the GAO found	
	33:10 specifically that that additional guidance	
	33:11 would be beneficial, correct?	
	33:12 A. Well, if they are making a	
	33:13 recommendation, then they are recommending that	
	33:14 the DEA take action on that front.	
34:05 - 34:05	Strait, Matthew 05-31-2019 (00:00:07)	MS04.22
	34:5 Q. Let's turn to Page 27 of the report,	P-20012.34.1
34:06 - 34:18	Strait, Matthew 05-31-2019 (00:00:42)	MS04.23
	34:6 the second paragraph about two-thirds of the	P-20012.34.2
	34:7 way down, beginning with "Additionally."	
	34:8 Do you see that?	
	34:9 A. I do.	
	34:10 Q. Can you read that sentence?	

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34:11 - 34:20	<p>34:11 A. "Additionally, in the absence of</p> <p>34:12 clear guidance from DEA, our survey data show</p> <p>34:13 that many distributors are setting thresholds</p> <p>34:14 on the amount of certain controlled substances</p> <p>34:15 that can be ordered by their customers, i.e.,</p> <p>34:16 pharmacies and practitioners, which can</p> <p>34:17 negatively impact pharmacies and ultimately</p> <p>34:18 patients' access."</p> <p>Strait, Matthew 05-31-2019 (00:00:02)</p>	MS04.24
34:21 - 35:04	<p>34:19 Q. Does the DEA agree with that</p> <p>34:20 statement?</p> <p>Strait, Matthew 05-31-2019 (00:00:36)</p> <p>34:21 A. I would say that this sentence is</p> <p>34:22 talking about what distributors told GAO. And</p> <p>34:23 I think that G -- we would agree that arbitrary</p> <p>34:24 thresholds set by a pharmacy -- or excuse me --</p> <p>34:25 by a distributor could create supply access</p> <p>35:1 issues.</p> <p>35:2 But on the flip side, I would say</p> <p>35:3 that those types of arbitrary thresholds could</p> <p>35:4 actually create oversupplies as well.</p> <p>Strait, Matthew 05-31-2019 (00:06:16)</p>	MS04.25
37:02 - 42:05	<p>37:2 Q. Okay. GAO was provided -- or GAO</p> <p>37:3 provided DEA with a draft of this particular</p> <p>37:4 report prior to its publication, correct?</p> <p>37:5 A. Correct.</p> <p>37:6 Q. And Mr. Joseph Rannazzisi responded</p> <p>37:7 in a letter on behalf of DEA, correct?</p> <p>37:8 A. That is --</p> <p>37:9 Q. And who --</p> <p>37:10 A. -- correct.</p> <p>37:11 Q. -- who is Joseph Rannazzisi?</p> <p>37:12 A. So Joseph Rannazzisi, at the time</p> <p>37:13 this report came out, was the deputy assistant</p> <p>37:14 administrator for the diversion control -- or</p> <p>37:15 the Office of Diversion Control. So he would</p> <p>37:16 have been the person who ran the diversion --</p> <p>37:17 the diversion control program.</p> <p>37:18 Q. And -- and DEA's position was that</p> <p>37:19 additional guidance was not necessary?</p>	MS04.26 clear

37:20 A. That is correct. DEA explained the
37:21 multitude in -- of ways in which its already
37:22 communicated in this case with distributors.

37:23 Q. And DEA's position was that the --
37:24 the text of the suspicious order regulation
37:25 itself was sufficiently straightforward,
38:1 correct?

38:2 A. It had been in place for 40 -- at
38:3 the time of this publication, probably 45
38:4 years; and that it was well understood by our
38:5 DEA registrant community; and that we did not
38:6 see a -- a need to expand upon it.

38:7 Q. And -- and be -- in part because the
38:8 DEA's position was that it was sufficiently
38:9 straightforward.

38:10 A. I -- I think that's correct, yes.

38:11 Q. And the -- but the GAO found in its
38:12 survey that many registrants did not feel that
38:13 it was well understood and, in fact, wanted
38:14 more guidance, correct?

38:15 A. Survey respondents did show that
38:16 they would like more guidance.

38:17 Q. More than half of the distributors
38:18 who -- who commented on that said -- said that,
38:19 right?

38:20 A. Yeah. And I -- I want to make a
38:21 point of clarification on that.

38:22 If -- if we -- if we go to Table 21,
38:23 which is something that I think is -- is
38:24 necessary to point out -- remember we have 750
38:25 controlled substance distributors at present.

39:1 The survey asked a number of questions. And
39:2 then it's asked some open-ended questions. And
39:3 you're obviously referring to the open-ended
39:4 questions.

39:5 But like we said at the outset, they
39:6 sent 200 surveys out to distributors. They
39:7 received 77 responses on a question to
39:8 distributors about guidance that -- that DEA
39:9 provided.

P-20012.73.1

P-20012.73.2

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39:10 And to your point, there was a

39:11 portion of those 77 who asked for more

39:12 guidance.

39:13 Q. Fair enough.

39:14 The DEA also told the GAO that,

clear

39:15 short of providing arbitrary thresholds to

39:16 distributors, it cannot provide more specific

39:17 suspicious orders guidance because the

39:18 variables that indicate a suspicious order

39:19 differ among distributors and their customers,

39:20 correct?

39:21 A. Can -- can you point that out on

39:22 the --

39:23 Q. Sure. Page -- give me one second.

39:24 It's -- it's in the -- the letter that Joseph

39:25 Rannazzisi sent. On Page 81 of the report,

P-20012.88

40:1 Page 5 of the letter.

40:2 A. Okay.

40:3 Q. Second -- or first full paragraph,

40:4 last sentence.

P-20012.88.1

40:5 Would you read that for the record?

40:6 A. Sure.

40:7 "Short of providing arbitrary

40:8 thresholds to distributors, DEA cannot provide

40:9 more specific suspicious orders guidance as the

40:10 variables that indicate an order is suspicious

40:11 are very fact-intensive and differ from

40:12 distributor to distributor and from customer to

40:13 customer."

40:14 Q. Can you explain what that means?

40:15 A. Yes, I -- I can. So DEA -- we have

40:16 long understood that distributors would like

40:17 nothing more than for DEA to tell them how much

40:18 an average pharmacy should be able to purchase.

40:19 And then they could use DEA's assessment as

40:20 a -- to set a threshold. And that would give

40:21 them the opportunity to, you know, basically

40:22 say that that's a DEA-established threshold.

40:23 What we've said is, with 71,000

40:24 DEA-registered pharmacies and 18,000 hospitals

40:25 and 1,700 narcotic treatment programs, all of
 41:1 the types of customers that distributors sell
 41:2 to, we can't do that.
 41:3 Because, quite frankly, the
 41:4 circumstances on what is appropriate for one
 41:5 pharmacy may be completely different than the
 41:6 requirements of another pharmacy. It's based
 41:7 on the population. It's based on the types of
 41:8 patients that are bringing prescriptions in to
 41:9 pharmacies or -- or being dispensed or
 41:10 administered at hospitals. It's the based on a
 41:11 number of different factors.
 41:12 And pharmacies that are around the
 41:13 corner from one another may have vastly
 41:14 different profiles that are acceptable.
 41:15 So DEA feels very strongly that that
 41:16 is something that only a distributor can know.
 41:17 Because a distributor is going to have much
 41:18 more of a working knowledge of who their
 41:19 customers are, more so than DEA.
 41:20 And I would argue that, if you end
 41:21 up setting an arbitrary limit on how much can
 41:22 be distributed by -- if DEA were to do this,
 41:23 you could inadvertently create a shortage of a
 41:24 situation if that amount is not sufficient. Or
 41:25 on the flip side, if the -- if that number is
 42:1 too high, you could actually create overages;
 42:2 and therefore, DEA is of the opinion that
 42:3 increases in availability could have the
 42:4 unintended consequence of increasing diversion
 42:5 and abuse.

42:06 - 42:19

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MS04.27

42:6 Q. And so DEA was not willing to
 42:7 provide additional guidance -- more specific
 42:8 suspicious order guidance than what is in the
 42:9 regulation itself?
 42:10 A. At the time that this letter went
 42:11 out, that is accurate.
 42:12 Q. And the regulation itself defines a
 42:13 suspicious order as an order of unusual size,

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	42:14 deviating substantially from the normal 42:15 pattern, or an order of unusual frequency, 42:16 correct? 42:17 A. That's sounds correct. 42:18 Q. And -- and the regulation does not 42:19 say what an unusual size means, correct?	
42:21 - 42:22	Strait, Matthew 05-31-2019 (00:00:03)	MS04.28
	42:21 THE WITNESS: It does not go on to 42:22 define any of those terms.	
42:24 - 43:02	Strait, Matthew 05-31-2019 (00:00:14)	MS04.29
	42:24 Q. And at the time that this letter was 42:25 written, the DEA had not provided additional 43:1 specific written guidance as to what unusual 43:2 size, frequency or pattern means, correct?	
43:04 - 43:22	Strait, Matthew 05-31-2019 (00:01:02)	MS04.30
	43:4 THE WITNESS: That is correct. 43:5 Although I want the qualify that by saying 43:6 nothing as it pertains to what I think they 43:7 distributors wanted, which was something in 43:8 writing. 43:9 DEA was certainly increasing its 43:10 liaison opportunities with the distributor 43:11 community in terms of distributor conferences 43:12 that we held in '13, '15 and '16; kind of 43:13 one-on-one engagements through what's known as 43:14 our distributor initiative, which we initiated 43:15 back in 2011 and continues to this day. 43:16 And so I think, with a very limited 43:17 registrant population -- they represent, what, 43:18 0.06 percent of our DEA registrant population, 43:19 if not slightly less -- that the one-on-one 43:20 interaction we believe in -- in a -- in a 43:21 person-to-person, face-to-face environment 43:22 is -- is better.	
43:23 - 43:25	Strait, Matthew 05-31-2019 (00:00:09)	MS04.31
	43:23 Q. But no written -- but you mentioned 43:24 no additional written guidance, correct? 43:25 A. At the time of this letter, no.	
44:01 - 44:13	Strait, Matthew 05-31-2019 (00:00:34)	MS04.32
	44:1 Q. Okay. In its report GAO responded	

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	44:2 to the DEA's letter, right?	
	44:3 A. Can you repeat the question.	
	44:4 Q. In -- in its report, the GAO	
	44:5 addressed what the DEA said in its letter,	
	44:6 correct?	
	44:7 A. Yes.	
	44:8 Q. And notwithstanding the DEA's	
	44:9 comments on the draft report, the GAO still	
	44:10 found that the DEA could provide additional	
	44:11 guidance to distributors, right?	
	44:12 A. Can you point to what -- what you're	
	44:13 referring to?	
44:14 - 44:14	Strait, Matthew 05-31-2019 (00:00:02)	MS04.33
	44:14 Q. Turning to Page 44, it says:	P-20012.51
44:15 - 46:04	Strait, Matthew 05-31-2019 (00:01:50)	MS04.34
	44:15 "Agency comments and our evaluation."	P-20012.51.2
	44:16 A. Yeah.	
	44:17 Q. Do you see that?	
	44:18 A. Yes, I do.	
	44:19 Q. And so this is the section in which	
	44:20 the GAO is responding to the Department of	
	44:21 Justice's response, correct?	
	44:22 A. Yes.	
	44:23 Q. And on page 45, it acknowledges	P-20012.52.1
	44:24 the -- the DEA's concerns about our second	
	44:25 recommendation to solicit input from	
	45:1 distributors or associations representing	
	45:2 distributors and to develop additional guidance	
	45:3 for distributors, right?	
	45:4 A. Yes.	
	45:5 Q. Then on page -- well, let's -- let's	
	45:6 walk through some of these.	
	45:7 It goes on to say that -- to repeat	P-20012.52.2
	45:8 what we just talked about, that short of	
	45:9 providing arbitrary thresholds to distributors,	
	45:10 it cannot provide more specific suspicious	
	45:11 orders guidance, right?	
	45:12 A. Yes.	
	45:13 Q. The -- the GAO is summarizing the	
	45:14 DEA's letter.	

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45:15	A. The DEA's comment. That's correct.	
45:16	Q. And it says: "Instead, DEA	P-20012.52.3
45:17	highlighted regulations that require	
45:18	distributors to design and operate systems to	
45:19	disclose suspicious orders," right?	
45:20	A. Correct. Yes.	
45:21	Q. And it says: "However, according to	P-20012.52.4
45:22	DEA's customer service plan for registrants,	
45:23	DEA is responsible for developing guidance for	
45:24	registrants regarding the CSA and its	
45:25	regulations. And the agency was able to create	
46:1	such guidance for pharmacy and practitioner	
46:2	registrants."	
46:3	Did I read that correctly?	
46:4	A. That is correct.	
46:05 - 47:01	Strait, Matthew 05-31-2019 (00:01:09)	MS04.35
46:5	Q. Turning to Page 46, that same	P-20012.53
46:6	paragraph toward the end, the GAO -- well,	
46:7	would you please read the sentence beginning	
46:8	with "Therefore."	
46:9	A. "Therefore, we continue to believe	P-20012.53.1
46:10	that DEA could provide additional written	
46:11	guidance for distributors that could be more	
46:12	widely accessible to all distributor	
46:13	registrants."	
46:14	Q. So here the GAO is not only	
46:15	recommending additional guidance but additional	
46:16	written guidance, correct?	
46:17	A. Correct.	
46:18	Q. And the GAO had -- had found that	
46:19	the DEA has created guidance manuals for	
46:20	pharmacists and practitioners like doctors but	
46:21	not distributors, right?	
46:22	A. Yes.	
46:23	Q. Is it true that the DEA had created	
46:24	manuals for pharmacists and practitioners about	
46:25	their regulatory obligations?	
47:1	A. Yes.	
47:05 - 47:10	Strait, Matthew 05-31-2019 (00:00:13)	MS04.36
47:5	Q. I'm showing you what has been marked	

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	47:6 as Exhibit 4.	
	47:7 Why don't you keep that report close	
	47:8 and hand. Because we'll --	
	47:9 A. Come back to it?	
	47:10 Q. -- be coming back to it. Thanks.	
47:11 - 48:16	Strait, Matthew 05-31-2019 (00:01:42)	MS04.37
	47:11 Can you identify this document?	
	47:12 A. This is DEA's pharmacist manual.	DEF-WV-619.1.1
	47:13 Q. So this is one of the -- one of the	
	47:14 two manuals that we just spoke about that DEA	
	47:15 has provided to -- to registrants but not to	
	47:16 distributors, correct?	
	47:17 A. Yeah. We would not provide this to	
	47:18 distributors. But yes, we -- this is a	
	47:19 document that is provided for the benefit of	
	47:20 our 71,000 retail pharmacies nationwide.	
	47:21 Q. And if we turn to -- just after	DEF-WV-619.1
	47:22 the -- the table of contents, at -- at -- let's	
	47:23 see. Where is this? Actually, just before the	
	47:24 table of contents. This is the very second	DEF-WV-619.2
	47:25 page of the document -- notes that: "This	DEF-WV-619.2.1
	48:1 manual has been prepared by the Drug	
	48:2 Enforcement Administration Office of Diversion	
	48:3 Control as a guide to assist pharmacists in	
	48:4 their understanding of the federal Controlled	
	48:5 Substances Act and its implementing regulations	
	48:6 as they pertain to the pharmacy profession."	
	48:7 Did I read that correctly?	
	48:8 A. That is correct.	
	48:9 Q. And this manual is a total of --	DEF-WV-619.1
	48:10 let's see -- 79 pages, correct?	
	48:11 A. Correct.	
	48:12 Q. And it provides additional written	
	48:13 -- additional written guidance to pharmacists	
	48:14 about how they can comply with the CSA and its	
	48:15 regulations in -- in the course of their	
	48:16 profession, correct?	
48:18 - 48:25	Strait, Matthew 05-31-2019 (00:00:14)	MS04.38
	48:18 THE WITNESS: It is a summary	
	48:19 document of the rules and regulations	

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Page/Line	Source	ID
	48:20 pertaining to DEA registrants.	
	48:21 BY MR. MASTERS:	
	48:22 Q. And it explains those -- those --	
	48:23 those regulations and -- and gives them	
	48:24 guidance on how to follow them in their	
	48:25 professional practice, correct?	
49:03 - 49:13	Strait, Matthew 05-31-2019 (00:00:25)	MS04.39
	49:3 Q. That's what we just read.	
	49:4 A. Yeah. I -- I'm -- I'm -- that's	
	49:5 fine. Yes. I agree.	
	49:6 Q. Okay. And is it also true that, at	clear
	49:7 the time of this report, DEA had not developed	
	49:8 a guidance manual or comparable document to the	
	49:9 one we just looked at for distributor	
	49:10 registrants?	
	49:11 A. Yes.	
	49:12 Q. And GAO here recommended that you	
	49:13 create one.	
49:16 - 50:10	Strait, Matthew 05-31-2019 (00:00:55)	MS04.40
	49:16 THE WITNESS: GAO recommended	
	49:17 additional written guidance or additional	
	49:18 guidance. And that is something that is	
	49:19 currently required in order to close out this	
	49:20 remaining open recommendation.	
	49:21 BY MR. MASTERS:	
	49:22 Q. And has DEA provided that to	
	49:23 distributors yet?	
	49:24 A. It's deliberative. We are	
	49:25 actually -- as you may know, in fall of 2017,	
	50:1 DEA -- the Department of Justice added to its	
	50:2 unified agenda suspicious order reporting as a	
	50:3 regulatory priority. So there will be written	
	50:4 guidance in the form of a notice of proposed	
	50:5 rule making published in the Federal Register.	
	50:6 And that's an effort that was added to the	
	50:7 unified agenda in the fall of '17.	
	50:8 Q. And has -- has -- as of today, what	
	50:9 is the status of this recommendation from the	
	50:10 GAO?	
50:16 - 51:13	Strait, Matthew 05-31-2019 (00:01:07)	MS04.41

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	50:16 THE WITNESS: I will be very 50:17 careful. Because obviously, as a deliberative 50:18 document, we can't talk about the details of 50:19 what may or may not be in it. But it does 50:20 remain under review within the executive 50:21 branch. 50:22 BY MR. MASTERS: 50:23 Q. So as of today, DEA has not provided 50:24 to -- to -- to distributors the additional 50:25 written guidance called for by the GAO in this 51:1 report? 51:2 A. Beyond the stuff that we've already 51:3 discussed pertaining to our continued efforts 51:4 to work with registrants directly, put -- 51:5 barring that aside, yes. 51:6 The reg -- the regulation, once 51:7 published, we understand from GAO, will be the 51:8 basis by which this recommendation can be 51:9 closed. 51:10 Q. And just to be clear, as of today, 51:11 the DEA has not provided the additional written 51:12 guidance that GAO recommended to distributors 51:13 as of today, correct?	
51:16 - 51:17	Strait, Matthew 05-31-2019 (00:00:03) 51:16 THE WITNESS: It remains an open 51:17 recommendation.	MS04.42
65:08 - 65:12	Strait, Matthew 05-31-2019 (00:00:07) 65:8 (Deposition Exhibit 8 was marked for 65:9 identification.) 65:10 BY MR. MASTERS: 65:11 Q. Showing you what has been marked as 65:12 Exhibit 8. It's a -- a double-sided document.	MS04.43
65:13 - 66:17	Strait, Matthew 05-31-2019 (00:01:32) 65:13 The Bates stamp for this document is 65:14 US-DEA 00026833, correct? 65:15 A. Correct. 65:16 Q. Can you identify this document? 65:17 A. This is taken from the GAO's web 65:18 site. And it represents a summary and status 65:19 of reports and open recommendations.	P-9229.1 MS04.44 P-9229.1.1

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65:20	Q. And specifically the status report	P-9229.1.2
65:21	-- the status of -- that the GAO is referring	
65:22	to here is the status of recommendations	
65:23	relating to the 2015 report that the DEA --	
65:24	that more DEA information about registrants'	
65:25	controlled substances roles could improve their	
66:1	understanding and help ensure access, correct?	
66:2	A. Correct.	
66:3	Q. At the bottom there, it appears that	P-9229.1.3
66:4	there is a table with the column on the left	
66:5	describing the recommendation and the column on	
66:6	the right describing the status and comments	
66:7	from GAO; is that correct?	
66:8	A. Yes.	
66:9	Q. And the second recommendation, which	P-9229.1.4
66:10	again is the one relating to distributors,	
66:11	appears to cover the end of the first page and	
66:12	onto the second page, right?	
66:13	A. Yes.	
66:14	Q. And at this point, the -- the GAO's	
66:15	web site indicates that the status of that	
66:16	second recommendation is open, correct?	P-9229.1.5
66:17	A. Yes.	
69:15 - 69:25	Strait, Matthew 05-31-2019 (00:00:30)	MS04.45
69:15	Q. Okay. As of now, the second quarter	
69:16	of 2019, May 31st, and -- and almost four years	
69:17	after the GAO recommended that the DEA provide	
69:18	additional written guidance to distributors,	
69:19	has the DEA published a revised regulation in	
69:20	the Federal Register?	
69:21	A. No.	
69:22	Q. Has the DEA published a guidance	
69:23	manual or comparable document to the one that	
69:24	exists for pharmacists and practitioners?	
69:25	A. No.	
71:01 - 72:20	Strait, Matthew 05-31-2019 (00:01:49)	MS04.46
71:1	Q. I want you to flip to the back page	P-20012.91
71:2	of Exhibit 3, please. Well, I guess the last	
71:3	page, to be technical.	
71:4	The first section under that -- I'm	P-20012.91.1

71:5 at page -- it reads "The GAO's Mission."

71:6 Could you read that for me, please.

71:7 A. Sure.

71:8 "The Government Accountability

71:9 Office, the audit evaluation and investigative

71:10 arm of congress, exists to support congress in

71:11 meeting its constitutional responsibilities and

71:12 to help improve the performance and

71:13 accountability of the federal government for

71:14 the American people. GAO examines the use of

71:15 public funds; evaluates federal programs and

71:16 policies; and provides analyses,

71:17 recommendations and other assistance to help

71:18 congress make informed oversight, policy and

71:19 funding decisions. GAO's commitment to good

71:20 government is reflected in its core values of

71:21 accountability, integrity and reliability."

71:22 Q. Would you agree that that's the

71:23 mission of the GAO?

71:24 A. Yes.

71:25 Q. Essentially it's to -- it's the

72:1 audit, evaluation, investigative arm of

72:2 congress; is that right?

72:3 A. Yes.

72:4 Q. The GA -- GAO is not responsible for

72:5 enforcing the Controlled Substances Act, is it?

72:6 A. No.

72:7 Q. And when the GAO did this report

72:8 that we've been talking about today, Exhibit 3,

72:9 it wasn't looking at whether registrants were

72:10 in compliance with the Controlled Substances

72:11 Act, was it?

72:12 A. No.

72:13 Q. It wasn't looking at whether those

72:14 registrants have reported suspicious orders to

72:15 the DEA?

72:16 A. No.

72:17 Q. It wasn't looking at whether

72:18 registrants had maintained adequate suspicious

72:19 order monitoring systems, was it?

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72:20	A. No.	
73:05 - 74:08	Strait, Matthew 05-31-2019 (00:01:09)	MS04.47
73:5	Q. I'd like to direct you to Page 77 of	P-20012.84
73:6	the report, Exhibit 3, and No. 1 of the letter	P-20012.84.1
73:7	there.	
73:8	Could you read the first sentence of	
73:9	that paragraph, please.	
73:10	A. Of recommend -- of the first comment	
73:11	that DEA made or the first sentence of the	
73:12	first paragraph?	
73:13	Q. I'm looking specifically at Page 77,	
73:14	the letter to Linda Kohn dated May 25th,	
73:15	2015 --	
73:16	A. Uh-huh.	
73:17	Q. -- following "With respect to the G"	
73:18	-- "GAO report, DEA wishes to emphasize the	
73:19	following important facts."	
73:20	A. Yep. Okay.	
73:21	And read No. 1?	
73:22	Q. Yes, please.	
73:23	A. DEA's Office of Diversion Control is	
73:24	responsible for administering and enforcing the	
73:25	provisions of the CSA as they pertain to	
74:1	ensuring the availability of controlled	
74:2	substances for legitimate uses while preventing	
74:3	their availability for diversion. The office	
74:4	is not charged with reducing the illicit demand	
74:5	for controlled substances."	
74:6	Q. Would you agree that that's the	
74:7	responsibility of the DEA's Office of Diversion	
74:8	Control?	
74:10 - 74:10	Strait, Matthew 05-31-2019 (00:00:01)	MS04.48
74:10	THE WITNESS: Yes.	
74:11 - 74:12	Strait, Matthew 05-31-2019 (00:00:03)	MS04.49
74:11	BY MS. ELLIS:	
74:12	Q. What is the role of the DEA?	clear
74:17 - 74:21	Strait, Matthew 05-31-2019 (00:00:09)	MS04.50
74:17	Q. Let me direct you to Page 67 of the	
74:18	report, Exhibit 3.	
74:19	A. Sorry. What page?	

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74:22 - 75:06	<p>74:20 Q. Page 67.</p> <p>74:21 A. Okay.</p> <p>Strait, Matthew 05-31-2019 (00:00:20)</p> <p>74:22 Q. I may have the may -- wrong</p> <p>74:23 reference here.</p> <p>74:24 But would you agree that the DEA's</p> <p>74:25 role is the -- is the primary agency</p> <p>75:1 responsible for coordinating the drug</p> <p>75:2 enforcement activities of the United States?</p> <p>75:3 A. As it pertains to pharmaceutical</p> <p>75:4 drugs containing controlled substances, yes.</p> <p>75:5 Q. It's a law enforcement agency?</p> <p>75:6 A. It is.</p>	MS04.51
75:15 - 75:21	<p>Strait, Matthew 05-31-2019 (00:00:10)</p> <p>75:15 Q. You were asked some questions</p> <p>75:16 earlier about the difference between pharmacies</p> <p>75:17 and distributors. I want to direct your</p> <p>75:18 attention back to that portion of your</p> <p>75:19 testimony.</p> <p>75:20 Do you recall?</p> <p>75:21 A. Yes.</p>	MS04.52
75:22 - 76:14	<p>Strait, Matthew 05-31-2019 (00:00:45)</p> <p>75:22 Q. Do you know how many registrants</p> <p>75:23 there are total?</p> <p>75:24 A. Currently we have 1.815 million</p> <p>75:25 registrants.</p> <p>76:1 Q. Do you know how many of those are</p> <p>76:2 pharmacies?</p> <p>76:3 A. Approximately 71,000.</p> <p>76:4 Q. Do you know how many of those are</p> <p>76:5 distributors?</p> <p>76:6 A. Right now -- I think I said 750, but</p> <p>76:7 it might be 715. But it is somewhere between</p> <p>76:8 715 and 750.</p> <p>76:9 Q. 715 to 750 distributors and 71,000</p> <p>76:10 pharmacies.</p> <p>76:11 Does the number of distributors</p> <p>76:12 versus the number of pharmacies affect the way</p> <p>76:13 the DEA communicates with each of those</p> <p>76:14 different groups of registrants at all?</p>	MS04.53

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76:17 - 77:14	Strait, Matthew 05-31-2019 (00:01:13) 76:17 THE WITNESS: Yes. 76:18 BY MS. ELLIS: 76:19 Q. How so? 76:20 A. Obviously, with a -- with 1.8 76:21 million registrants, DEA has limited resources, 76:22 and it does need to think about how best to 76:23 prioritize those resources. 76:24 With our -- that portion of our drug 76:25 supply chain that handle the largest volumes of 77:1 controlled substances, i.e., our manufacturers 77:2 and our distributors, our engagement with them 77:3 tends to be more in person, one-on-one, and -- 77:4 and very much routine in terms of the frequency 77:5 by which we conduct audits and inspections of 77:6 those registrants. 77:7 And because of sheer numbers, our 77:8 guidance to those other portions of our 77:9 registrant community that are larger, i.e., 77:10 pharmacies, and prescribers, we do have to rely 77:11 more on providing them guidance on our 77:12 diversion control web site. And of course we 77:13 do still engage with them in person by offering 77:14 all sorts of different training opportunities.	MS04.54
77:22 - 78:04	Strait, Matthew 05-31-2019 (00:00:19) 77:22 Q. Let -- let's go to the -- Page 2, 77:23 the summary, I guess, of Exhibit 3. 77:24 What GAO recommends, this first 77:25 sentence on the bottom-left corner: "GAO 78:1 recommends that DEA takes three actions to 78:2 improve communication with" a -- "with and 78:3 guidance for registrants about their CSA roles 78:4 and responsibilities."	MS04.55 P-20012.2 P-20012.2.2
78:13 - 78:19	Strait, Matthew 05-31-2019 (00:00:14) 78:13 Q. You would agree that this report is 78:14 focused on guidance for registrants about their 78:15 CSA roles and responsibilities, correct? 78:16 A. Yes. 78:17 Q. And your testimony today has been 78:18 focused on this report, right?	MS04.56

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79:24 - 80:06	78:19 A. Correct. Strait, Matthew 05-31-2019 (00:00:27) 79:24 MS. ELLIS: Earlier you discussed 79:25 some of the things that the DEA -- some of the 80:1 actions that the DEA had taken in response to 80:2 the GAO's report. I want to ask you some 80:3 additional questions about what the DEA -- DEA 80:4 had done after this report at -- was issued. 80:5 I'm marking for the record 80:6 Exhibit 9.	MS04.57 clear P-44578.1
80:15 - 81:24	Strait, Matthew 05-31-2019 (00:01:36) 80:15 Q. Exhibit 9 is a e-mail that I believe 80:16 you reviewed in advance of today's deposition. 80:17 The Bates number is cut off a little at the 80:18 bottom, but for the record it's 80:19 US-DEA-00026799. 80:20 Do you recall reviewing this 80:21 document? 80:22 A. Yes. 80:23 Q. On the second page of the document, 80:24 it appears to be a letter. 80:25 What is this letter? 81:1 A. This would have been one of the 81:2 status update letters from our GAO audit 81:3 liaison section to GAO. And this one was dated 81:4 April 27th, 2016, which means that it would 81:5 have been very -- within a year or right around 81:6 a year after the report came out. 81:7 Q. Is this the first status update 81:8 letter that you're aware was issued following 81:9 the report? 81:10 A. No. Actually, the -- there is a 81:11 reference to the -- in the first paragraph to a 81:12 status response congressional letter dated 81:13 September 21st, 2015. 81:14 And what that means to me is that 81:15 congress probably wrote to ask about the 81:16 status. And in DEA's response to congress, it 81:17 would have sent a CC copy to GAO. 81:18 Q. So that -- that would have been	MS04.58 P-44578.1.1 P-44578.2 P-44578.2.1 P-44578.1.2

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	81:19 different than this type of letter?	P-44578.2
	81:20 A. Correct. But it could have been	
	81:21 similar.	
	81:22 Q. Similar but not directly to GAO.	
	81:23 Okay. I want to direct you to the	
	81:24 next page of the document, Section 2.	P-44578.3.1
81:25 - 85:02	Strait, Matthew 05-31-2019 (00:03:53)	MS04.59
	81:25 What is your understanding of the	
	82:1 DEA response in Section 2?	
	82:2 What is this in response to?	
	82:3 A. Page 2, this is DEA's response to	P-44578.3.2
	82:4 Recommendation 2 about guidance for -- for	
	82:5 distributors and those associations	
	82:6 representing distributors on their suspicious	
	82:7 order monitoring reporting obligations.	
	82:8 Q. You were asked a lot of questions	
	82:9 this morning about whether the DE -- DEA had	
	82:10 issued any written guidance to distributors	
	82:11 between the time that the report was issued and	
	82:12 today.	
	82:13 Does this section describe other	
	82:14 actions that the DEA took to educate	
	82:15 distributors about their responsibilities under	
	82:16 the CSA?	
	82:17 A. Yes.	
	82:18 Q. And what are some of the actions	
	82:19 that the DEA took during this time frame as	
	82:20 outlined in this letter?	
	82:21 A. So the first paragraph talks about	P-44578.3.3
	82:22 DEA's distributor conference, which it held in	
	82:23 2013, and then, as indicated here, held in 2015	
	82:24 and 2016.	
	82:25 The -- obviously what we go on to	P-44578.3.4
	83:1 say is that information provided during these	
	83:2 conferences are published on DEA's web site.	
	83:3 The third paragraph talks about	P-44578.3.5
	83:4 DEA's work with the National Association of	
	83:5 Boards of Pharmacy and a number of other	
	83:6 stakeholder groups, which includes some	
	83:7 associations representing various aspects of	

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83:8 our registrant population on a consensus
 83:9 document entitled "Stakeholders, Challenges and
 83:10 Red-Flag Warning Signs Related to Prescribing
 83:11 and Dispensing of Controlled Substances."

83:12 Q. Were all of these efforts by the DEA
 83:13 to comply with the GAO's recommendation to
 83:14 provide distributors further guidance under the
 83:15 CSA?

83:16 A. Yes.

83:17 Q. Were some of these written?

83:18 A. To the extent that the distributor
 83:19 conference presentations were -- are generally
 83:20 PowerPoint presentations and therefore are --
 83:21 are written documents, yes.

83:22 And the -- the NABP document, I
 83:23 actually did take a look at that. I did not
 83:24 see where DEA was actually noted as an author,
 83:25 which is the reason I didn't mention it during
 84:1 my -- my remarks earlier. So that I'm -- I'm
 84:2 not certain I can say with certainty that that
 84:3 would have constituted written DEA guidance.

84:4 Q. You mentioned, I think, in your
 84:5 earlier answer something about a distributor
 84:6 initiative and working directly with
 84:7 distributors.

84:8 Do you recall that testimony?

84:9 A. Absolutely. Yes.

84:10 Q. Would -- would this be a part of
 84:11 that?

84:12 A. So actually the distributor
 84:13 initiative is separate from the issues that are
 84:14 outlined in this response. But certainly DEA
 84:15 has indicated that one of the main ways in
 84:16 which it interacts with the distributor
 84:17 community is through what's called the
 84:18 distributor initiative, which I believe began
 84:19 in 2006.

84:20 And this is direct, one-on-one
 84:21 engagement with DEA registered distributors.
 84:22 And that's different from the distributor

clear

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	84:23 conference, which is a -- a number of DEA 84:24 registered distributors coming to a venue free 84:25 of charge, you know, to -- to receive 85:1 presentations from DEA and to collaborate with 85:2 DEA on -- on issues.	
88:11 - 89:12	Strait, Matthew 05-31-2019 (00:01:17)	MS04.60
	88:11 Q. In addition to the efforts described 88:12 in Exhibit 9, it appears that, in the third 88:13 paragraph of Exhibit 10, beginning with "DEA 88:14 has continued to work with distributors," there 88:15 is the description of two additional 88:16 conferences in 2016; is that right? 88:17 A. Correct. 88:18 Q. Could you read that aloud for the 88:19 jury, please. 88:20 A. Sure. 88:21 "DEA has continued its work with 88:22 distributors and associations by meeting with 88:23 industry upon request and providing guidance 88:24 and discussion related to suspicious orders. 88:25 DEA held two distributors and one reverse 89:1 distributors conference in 2016. These 89:2 conferences provided DEA with an excellent 89:3 opportunity to engage its distributor 89:4 registrants, attachment 4, about their roles 89:5 and responsibilities for monitoring and 89:6 reporting suspicious orders. DEA plans to host 89:7 yearly training for distributors and reverse 89:8 distributors, which will answer questions on 89:9 these issues." 89:10 Q. I want to direct you to Table 21 89:11 that you discussed earlier in Exhibit 3. And 89:12 that is on page --	P-19527.3.1
89:13 - 89:14	Strait, Matthew 05-31-2019 (00:00:04)	MS04.61
	89:13 A. 66?	
89:15 - 91:20	Strait, Matthew 05-31-2019 (00:02:32) 89:15 In your earlier testimony, I believe 89:16 you made the -- you clarified to say that the 89:17 GAO's recommendation, as you understood it, was	MS04.62

89:18 based on the response outlined in this table;
 89:19 is that right?
 89:20 A. Yes. And some -- and some of the --
 89:21 the -- they had an open-ended question, and
 89:22 then they had objective measures. And Table 21
 89:23 was representing answers to objective measures
 89:24 in their survey.

89:25 Q. And in Table 21, this reflects that

90:1 there were 77 total responses from

90:2 distributors; is that right?

90:3 A. Yes. I see one other thing that --

90:4 on this table representing distributors saying

90:5 that there may have been 78 responses. But

90:6 yes, 77 or 78 of the 200 that were -- that

90:7 received the opportunity to respond to their

90:8 survey.

90:9 Q. And you said a few moments ago that

90:10 there's between, now, 715 to 750 distributors.

90:11 Was that number different at the

90:12 time that this report was issued?

90:13 A. Yeah. The -- the number that's used

90:14 in the report is I believe 954. And I believe

90:15 the distinction there -- because I didn't go

90:16 back and look at where we were in 2014. But I

90:17 believe the difference is I'm talking about

90:18 controlled substance distributors.

90:19 We also have a population of

90:20 registrants that are involved in the

90:21 distribution of List I chemicals. So I'm

90:22 excluding the List I chemical population from

90:23 my numbers.

90:24 Q. Would the number -- what would the

90:25 number of controlled substances distributors

91:1 have been around the time that this report was

91:2 issued, if you know?

91:3 A. I think it would have been

91:4 comparable to what -- the numbers that we have

91:5 now. I don't think we've seen any drastic

91:6 changes in the size of our registrant

91:7 population for DEA-registered distributors.

P-20012.73.2

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	91:8 Q. So directing your attention back to	
	91:9 Table 1.	
	91:10 Of those that responded to the	
	91:11 survey -- let's look at this first line here.	
	91:12 Here you see the 77 responses,	
	91:13 correct, is in respect to the DEA's Know Your	
	91:14 Customer guidance, right?	
	91:15 A. Yes.	
	91:16 Q. Okay. And what is the total number	
	91:17 of distributors that they said -- that thought	
	91:18 that the DEA's feedback was very or moderately	P-20012.73.3
	91:19 helpful?	
	91:20 A. So it's about two --	
91:22 - 92:07	Strait, Matthew 05-31-2019 (00:00:20)	MS04.63
	91:22 THE WITNESS: It's approximately	
	91:23 two-thirds of the registrants that did respond	
	91:24 to this question indicated that they found	
	91:25 DEA's guidance to be very or moderately	
	92:1 helpful.	
	92:2 BY MS. ELLIS:	
	92:3 Q. A majority.	
	92:4 A. A majority, yes.	
	92:5 Q. And how many, according to this	
	92:6 chart, found that it was only slightly or not	P-20012.73.4
	92:7 helpful at all?	
92:10 - 92:11	Strait, Matthew 05-31-2019 (00:00:03)	MS04.64
	92:10 THE WITNESS: The number here is 28	
	92:11 of 77.	
94:25 - 95:02	Strait, Matthew 05-31-2019 (00:00:07)	MS04.65
	94:25 Q. Are you aware of whether the GA	clear
	95:1 [sic] solicited input from registrants into the	
	95:2 content of the survey?	
95:04 - 95:07	Strait, Matthew 05-31-2019 (00:00:04)	MS04.66
	95:4 THE WITNESS: I don't know the	
	95:5 answer to that question, no.	
	95:6 BY MS. ELLIS:	
	95:7 Q. Would that surprise you?	
95:09 - 95:14	Strait, Matthew 05-31-2019 (00:00:13)	MS04.67
	95:9 THE WITNESS: Yes. That would	
	95:10 probably surprise me a little bit.	

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95:11	BY MS. ELLIS:	
95:12	Q. Are you aware that the GAO solicited	
95:13	input into this report and the survey as early	
95:14	as July of 2013 --	
95:18 - 95:22	Strait, Matthew 05-31-2019 (00:00:10)	MS04.68
95:18	Q. -- from registrants?	
95:19	A. Can you repeat that.	
95:20	Q. Are you aware that the GAO solicited	
95:21	input into the survey and report from	
95:22	registrants as early as July of 2013?	
96:01 - 96:01	Strait, Matthew 05-31-2019 (00:00:01)	MS04.69
96:01	THE WITNESS: And the answer is no.	
96:02 - 96:05	Strait, Matthew 05-31-2019 (00:00:10)	MS04.70
96:02	BY MS. ELLIS:	
96:03	Q. Are you aware that in August of 2013	
96:04	the GAO participated in a conference call with	
96:05	the HDMA staff regarding this report?	
96:09 - 96:09	Strait, Matthew 05-31-2019 (00:00:02)	MS04.71
96:09	THE WITNESS: No. I am not aware.	
96:10 - 96:11	Strait, Matthew 05-31-2019 (00:00:02)	MS04.72
96:10	BY MS. ELLIS:	
96:11	Q. What is the HDMA; do you know?	
96:15 - 96:17	Strait, Matthew 05-31-2019 (00:00:05)	MS04.73
96:15	THE WITNESS: HDMA is now HDA. And	
96:16	I believe they're the Healthcare Distributor	
96:17	Alliance.	
98:21 - 98:25	Strait, Matthew 05-31-2019 (00:00:08)	MS04.74
98:21	Q. You said they were on the hill	
98:22	talking about their representatives' concern	
98:23	over the amount of communication that they had	
98:24	with the DEA.	
98:25	What do you mean?	
99:03 - 99:14	Strait, Matthew 05-31-2019 (00:00:33)	MS04.75
99:03	THE WITNESS: So HDMA, HDA is a --	
99:04	is a lobbying firm that represents the	
99:05	interests of -- of their clients on Capital	
99:06	Hill. And they were very vocal. And they've	
99:07	actually testified alongside DEA witnesses at	
99:08	hearings in which these -- these issues were	
99:09	brought up in terms of communication with the	

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	99:10 agency.	
	99:11 BY MS. ELLIS:	
	99:12 Q. Do you understand that they've tried	
	99:13 to influence the way the DEA communicates with	
	99:14 registrants?	
99:19 - 99:19	Strait, Matthew 05-31-2019 (00:00:01)	MS04.76
	99:19 THE WITNESS: Yes.	
104:16 - 104:23	Strait, Matthew 05-31-2019 (00:00:19)	MS04.77
	104:16 (Deposition Exhibit 12 was marked	
	104:17 for identification.)	
	104:18 BY MS. ELLIS:	
	104:19 Q. Handing you what's been marked for	P-44579.1
	104:20 the record as Exhibit 12.	
	104:21 Are you aware that the GAO held a	
	104:22 meeting with industry representatives,	
	104:23 including CSA, registrants in October of 2014?	
105:01 - 105:01	Strait, Matthew 05-31-2019 (00:00:02)	MS04.78
	105:1 THE WITNESS: I am not, no.	
105:02 - 106:20	Strait, Matthew 05-31-2019 (00:01:56)	MS04.79
	105:2 BY MS. ELLIS:	
	105:3 Q. Would you read the first two	
	105:4 sentences of the top of that e-mail for me,	
	105:5 please.	
	105:6 A. Starting with "I'll ask Carl"?	
	105:7 Q. Yes.	
	105:8 A. "I'll ask Carl. As to HDMA, here	P-44579.1.1
	105:9 are my thoughts."	
	105:10 Keep going.	
	105:11 Q. Yes, please.	
	105:12 A. Okay. "First, in my discussions	P-44579.1.2
	105:13 with HDMA, they have told me that they were	
	105:14 involved in helping to create the survey. So	
	105:15 I'm assuming they have already provided their	
	105:16 input to the GAO. Second, not sure if this	
	105:17 meeting at NASCSA is just for industry (and not	
	105:18 trade groups) given it's targeted specifically	
	105:19 towards industry representatives. I can ask	
	105:20 HDMA if they are going/got an invitation."	
	105:21 Keep going?	
	105:22 Q. Sure. Go ahead.	

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105:23	A. "Lastly, not sure we want Linden	P-44579.1.3
105:24	there at this event if we're trying to keep a	
105:25	low profile (and not sure he can go without	
106:1	specifying for whom he is attending)."	
106:2	Keep reading?	
106:3	Q. Just go ahead and --	
106:4	A. Okay.	
106:5	Q. -- read the next two sentences.	
106:6	A. "My overall concern with this is	P-44579.1.4
106:7	that we got burned before with the GAO. And	
106:8	I'm not sure how much we want to be perceived	
106:9	as being on the front end with them. I think	
106:10	we've worked towards coordinating a common	
106:11	theme from our industry colleagues (via our	
106:12	work groups, Purdue, et cetera. Just not sure	
106:13	the downside of the potentially irritating DEA	
106:14	is worth the added benefit of showing up at	
106:15	this meeting where DEA reps most likely will be	
106:16	present at the NASCSA meeting. If you think	
106:17	other" -- "otherwise, let's decide who should	
106:18	go. Thanks, Bob."	
106:19	Q. Do you know if DEA reps were present	
106:20	at that NASCSA meeting?	
106:24 - 106:25	Strait, Matthew 05-31-2019 (00:00:02)	MS04.80
106:24	THE WITNESS: I don't. I don't know	
106:25	the answer.	
109:10 - 110:15	Strait, Matthew 05-31-2019 (00:01:38)	MS04.81
109:10	Q. We were just discussing Exhibit 8,	P-9229.1
109:11	which is the GAO summary available on their web	P-9229.1.1
109:12	site regarding the GAO report we've been	
109:13	discussing today.	
109:14	I would like to direct your	
109:15	attention to midway through the first	P-9229.1.6
109:16	paragraph. And there is a sentence there	
109:17	starting with "Of those."	
109:18	Do you see it?	
109:19	A. Yes.	
109:20	Q. Could you read that aloud, please.	
109:21	A. "Of those registrants that have	
109:22	interacted with DEA, most were generally	

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109:23 satisfied with those interactions. For
 109:24 example, 92 percent of distributors that
 109:25 communicated with DEA field office staff found
 110:1 them 'very' or 'moderately' helpful. However,
 110:2 some distributors, individual pharmacies and
 110:3 chain pharmacy corporate office want improved
 110:4 guidance from and additional communication with
 110:5 DEA about their CSA roles and responsibilities.
 110:6 For example, 36 of 55 distributors commented
 110:7 that more communication or information from or
 110:8 interactions with DEA would be helpful. DEA
 110:9 officials indicated that they do not believe
 110:10 there is a need for more registrant guidance or
 110:11 communication."
 110:12 Q. Do you understand that sentence to
 110:13 be the support for the GAO's Recommendation 2
 110:14 in that report?
 110:15 A. The --

110:17 - 111:12

Strait, Matthew 05-31-2019 (00:01:01)**MS04.82**

110:17 THE WITNESS: The 36 of 55?

110:18 MS. ELLIS: Yes.

110:19 THE WITNESS: I don't have a way of
 110:20 knowing what GAO was thinking in terms of
 110:21 crafting their recommendations. So I can't
 110:22 answer your question.

110:23 BY MS. ELLIS:

110:24 Q. Let's look at the second paragraph.

P-9229.1.7

110:25 If you could read that aloud, please.

111:1 A. "Officials GAO interviewed from 14
 111:2 of 16 state government agencies and 24 of 26
 111:3 national associations said they interact with
 111:4 DEA through various methods. 13 of 14 state
 111:5 agencies and 10 of 17 national associations
 111:6 that commented about their satisfaction with
 111:7 DEA interactions said they were generally
 111:8 satisfied. However, some associations wanted
 111:9 improved DEA communication."

111:10 Q. The next paragraph goes on to put a
 111:11 number on that, quote, some associations,
 111:12 doesn't it? The next sentence?

P-9229.1.8

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111:15 - 112:03	Strait, Matthew 05-31-2019 (00:00:32) 111:15 Q. Go ahead and read the next sentence 111:16 for the jury. 111:17 A. Okay. 111:18 "Because the additional 111:19 communication that four associations want 111:20 relates to their members' CSA roles and 111:21 responsibility, improved DEA communication with 111:22 and guidance for registrants may address some 111:23 of the associations concerns." 111:24 So yes to your question. Four is 111:25 the number. 112:1 Q. So is it your understanding that 112:2 Recommendation 2 was based, in part, on 112:3 feedback from four associations?	MS04.83
112:08 - 112:15	Strait, Matthew 05-31-2019 (00:00:16) 112:8 THE WITNESS: Yeah. Like I said, I 112:9 don't know what -- what specifically GAO was 112:10 thinking here. But it certainly seems 112:11 reasonable that -- that these concerns raised 112:12 by these associations may have informed their 112:13 decision making. 112:14 MS. ELLIS: I have no further 112:15 questions at this time.	MS04.84 clear
115:21 - 116:01	Strait, Matthew 05-31-2019 (00:00:22) 115:21 Q. You were also shown a document 115:22 reflecting a communication from DEA to GAO on 115:23 December 20th, 2016. I believe it was 115:24 Exhibit 10. 115:25 A. Yes.	MS04.85 P-19527.2.1
116:02 - 117:11	Strait, Matthew 05-31-2019 (00:02:04) 116:1 Q. And on the second page of the 116:2 letter -- I'll just go ahead and show you 116:3 this -- this has some of my highlighting, but I 116:4 want to direct you to the -- the paragraph -- 116:5 the second paragraph of DEA's response states 116:6 that: "The GAO survey was conducted in 2015 116:7 prior to new DEA leadership, including a new 116:8 acting administrator and new management for the 116:9 diversion control division. DEA's new	P-19527.3.2 MS04.86 P-19527.3.3

116:10 management met with industry leaders on
 116:11 February 29th, 2016. Since then DEA has
 116:12 continued to work with the industry and
 116:13 improved communication on these issues."

116:14 Did I read that correctly?

116:15 A. Yes.

116:16 Q. In -- in the DEA's response to the
 116:17 GAO and the DEA's status report to the GAO, why
 116:18 did the DEA referenced [sic] new leadership and
 116:19 new management?

116:20 A. So there was a -- a recognition that
 116:21 in -- was it July of 2015 DEA got a new
 116:22 administrator. That was shortly after the
 116:23 former administrator, Michele Leonhart,
 116:24 retired. And one of Acting Administrator
 116:25 Rosenberg's first orders of business was to
 117:1 work more in a collaborative fashion with our
 117:2 registrant community.

117:3 And so, in -- in -- along that side,
 117:4 he also decided to identify a new person that
 117:5 would run the diversion control program. And
 117:6 that resulted in the former head of diversion
 117:7 retiring.

117:8 Q. And this introduction of new
 117:9 management and new leadership in the DEA Office
 117:10 of Diversion Control and at the DEA resulted in
 117:11 improved communications on these issues, fair?

117:14 - 118:01

Strait, Matthew 05-31-2019 (00:00:33)

MS04.87

117:14 THE WITNESS: The February 29th,
 117:15 2016 meeting was a listening session. So this
 117:16 was our opportunity to basically hear from our
 117:17 trade associations as to things that they
 117:18 wanted to communicate with DEA about.

117:19 BY MR. MASTERS:

117:20 Q. And the DEA's new management felt
 117:21 that that was a priority?

117:22 A. That was something we absolutely
 117:23 wanted to do, yeah.

117:24 And I would say that, under the
 117:25 leadership of Acting Administrator Rosenberg,

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121:10 - 122:03	118:1 that was a priority, yes. Strait, Matthew 05-31-2019 (00:01:04)	MS04.88
	121:10 Q. One final question: Counsel for 121:11 plaintiffs at -- at Exhibit 9, I believe it 121:12 was, reviewed a status report from April 27th, 121:13 2016, in which the DEA listed a number of 121:14 communications that it -- or a number of 121:15 efforts that it took to comply with the GAO's 121:16 recommendation. 121:17 And I just want to confirm for the 121:18 record that the GAO, in response to this 121:19 letter, did not close the recommendation, 121:20 correct? 121:21 A. They did not close the 121:22 recommendation despite our request that they do 121:23 so. 121:24 Q. And in -- and in June of 2016, the 121:25 GAO stated that additional written guidance is 122:1 still -- has still not occurred and is -- and 122:2 is needed in order to satisfy and close the 122:3 recommendation, correct?	P-44578.2 P-44578.2.2
122:06 - 122:14	Strait, Matthew 05-31-2019 (00:00:18) 122:6 THE WITNESS: I would just refer you 122:7 to the -- the plain language in -- in Exhibit 122:8 8, which talks about the status as indicated by 122:9 GAO on their web site. And I can read that if 122:10 you'd like. 122:11 BY MR. MASTERS: 122:12 Q. Which -- which is still open, 122:13 correct? 122:14 A. It is still open, yes.	MS04.89

Plaintiffs Affirmative Designations = 00:34:31

Defense Counter Designations = 00:04:20

Plaintiff Counter Counters = 00:03:05

Defense Completeness Counters = 00:22:58

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